

RICK D. NYDEGGER
BRENT P. LORIMER
THOMAS R. VUJINICK
LARRY R. LAYCOCK
JONATHAN W. REYNOLDS
DAVID R. WRIGHT
JOHN C. STRINGHAM
JOHN M. GUYNN
CHARLES L. ROBERTS
DANA L. TANGREN
ERIC L. MASCHOFF
CHARLES J. VEVERKA
ROBYN L. PHILLIPS
RICHARD C. GILMORE *
STERLING A. BRENNAN
R. BURNS ISRAELEN
DAVID R. TODD
GREGORY M. TAYLOR
DAVID B. DELLENBACH
L. DAVID GRIFFIN
ADRIAN J. LEE
FRASER D. ROY
CARL T. REED



WORKMAN | NYDEGGER

INTELLECTUAL PROPERTY ATTORNEYS

1000 EAGLE GATE TOWER
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UTAH 84111
TELEPHONE: (801) 533-9800
FAX: (801) 328-1707
WEBSITE: HTTP://WWW.WNLAW.COM

EXPRESS MAIL LABEL NO. EV443087844US

PATENT APPLICATION
Docket No. 15070.6.2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

B. Ron Johnson

Serial No. 10/816,571

Confirmation No. 1232

Filed: April 1, 2004

For: ANTI-INFECTIVE COMPOSITIONS, METHODS)
AND SYSTEMS FOR TREATING PATHOGEN-)
INDUCED DISORDERED TISSUES)

Examiner: Not yet known

) Art Unit
) 1614



R. PARRISH FREEMAN, JR.
PETER F. MALEN, JR.
L. REX SEARS, PH.D.
WILLIAM R. RICHTER
ERIC M. KAMERATH
ROBERT E. AYCOCK
JENS C. JENKINS
KEVIN W. STINGER
WILLIAM J. ATHAY
MICHAEL B. DODD
RYAN D. BENSON
SARA D. JONES
TIGER KELLER
JANNA L. JENSEN
MATTHEW D. TODD
J. LAVAR OLDHAM
MICHAEL J. FRODSHAM
JOSEPH L. KRUPA
BRETT A. HANSEN
BRETT I. JOHNSON
MATTHEW A. BARLOW
WESLEY C. ROSANDER
ANDREW S. HANSEN
CHAD E. NYDEGGER
JOSEPH G. PIA
CLINTON E. DUKE
DAVID J. LORENZ †
RYAN N. FARR *
JAMES B. BELSHE

TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing and pursuant to 37 C.F.R. § 1.97 is a Supplemental Information Disclosure Statement.

Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

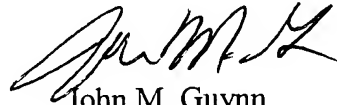
X Form PTO-1449 list of ninety-five (95) references submitted for consideration.

Because this Information Disclosure Statement is being filed prior to the mailing of the first substantive office action, no fee is required.

Please credit any over payment or charge any additional fees to Deposit Account No. 23-3178 of the undersigned.

Dated this 30th day of June 2004.

Respectfully submitted,



John M. Guynn
Attorney for Applicant
Registration No. 36,153
Customer No. 022913



Docket No. 15070.6.2

In re application of:

Examiner: Not yet known

1

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the enclosed art is the closest to the claimed invention (taken in its entirety) of which the undersigned is presently aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

Because each of the cited references is either a U.S. patent or a published U.S. application and/or was previously cited in a parent application relied upon for priority under 35 U.S.C. § 120, Applicant is not required to provide copies of any of the cited references.

DATED this 30th day of June 2004.

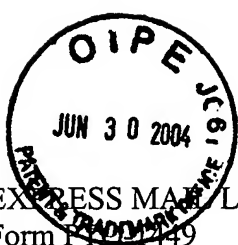
Respectfully submitted,

A handwritten signature in black ink, appearing to read "John M. Guynn", is written over the printed name.

John M. Guynn
Attorney for Applicant
Registration No. 36,153
Customer No. 022913
(801) 533-9800

JMG:mla

W:\15070\6.2\MLA0000001923V001.doc



EXPRESS MAIL LABEL NO.: EV 443087844 US
Form 149

Sheet 1 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

INFORMATION DISCLOSURE CITATIONS MADE BY APPLICANT

U.S. Patent Documents

<u>Examiner Initial*</u>	<u>Patent Number</u>	<u>Issue Date</u>	<u>Name</u>
____ 1	6,420,431	07/16/02	Johnson
____ 2	6,414,032	07/02/02	Johnson
____ 3	6,410,599	06/25/02	Johnson
____ 4	6,284,289	09/04/01	Van den Berghe
____ 5	6,211,243	04/03/01	Johnson
____ 6	5,827,870	10/27/98	Chodosh
____ 7	5,767,163	06/16/98	Kundsin
____ 8	5,762,940	06/09/98	Bourbon et al.
____ 9	5,753,270	05/19/98	Beauchamp et al.
____ 10	5,725,875	03/10/98	Noll et al.
____ 11	5,712,257	01/27/98	Carter
____ 12	5,709,866	01/20/98	Booras et al.

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 2 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

_____ 13	5,704,906	01/06/98	Fox
_____ 14	5,678,273	10/21/97	Porcelli
_____ 15	5,661,170	08/26/97	Chodosh
_____ 16	5,637,307	01/10/97	Simmons et al.
_____ 17	5,631,245	05/20/97	Drube
_____ 18	5,527,534	06/18/96	Myhling
_____ 19	5,503,853	04/02/96	Bollen et al.
_____ 20	5,492,932	02/20/96	Kundsin
_____ 21	5,439,685	08/08/95	Augros
_____ 22	5,405,602	04/11/95	Simmons et al.
_____ 23	5,387,611	02/07/95	Rubinstein
_____ 24	5,198,217	03/30/93	Vedros
_____ 25	5,137,724	08/11/92	Balzarini et al.
_____ 26	5,036,095	07/30/91	Andermann
_____ 27	5,016,651	05/21/91	Stalcup et al.
_____ 28	4,975,217	12/04/90	Brown-Skrobot et al.

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 3 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

_____ 29	4,957,734	09/18/90	Miller
_____ 30	4,952,204	08/28/90	Korteweg
_____ 31	4,929,442	05/29/90	Powell
_____ 32	4,895,727	01/23/90	Allen
_____ 33	4,887,994	12/19/89	Bedford
_____ 34	4,875,602	10/24/89	Chickering et al.
_____ 35	4,828,542	0509/89	Hermann
_____ 36	4,822,605	04/18/89	Powell
_____ 37	4,797,420	01/10/89	Bryant
_____ 38	4,661,354	04/28/87	Finnerty
_____ 39	4,507,281	03/26/85	Asculai et al.
_____ 40	4,486,450	12/04/450	Bernstein
_____ 41	4,394,381	07/19/83	Sherrill
_____ 42	4,390,539	06/28/83	Sherrill
_____ 43	4,262,007	04/14/81	Sherrill
_____ 44	4,183,684	01/15/80	Avery, Jr.

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 4 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

_____ 45	4,176,197	11/27/79	Olson
_____ 46	3,369,543	02/20/68	Ronco
_____ 47	1,822,566	09/08/31	Davies

Foreign Patent Documents

<u>Examiner Initial*</u>	<u>Document Number</u>	<u>Publ. Date</u>	<u>Country or Patent Office</u>	<u>Class</u>	<u>Sub Class</u>	<u>Trans- lation</u>
_____ 48	2,143,136	08/23/96	Canada	6		---
_____ 49	2 700 698	07/29/94	France	3		Yes
_____ 50	0 478 445	09/24/91	France	3	48	
_____ 51	0 190 797	08/13/86	EPO	4		---
_____ 52	0 181 184	05/14/86	EPO	4		---
_____ 53	1 479 480	07/13/77	GB	2		
_____ 54	WO 99/08713	02/25/99	PCT	6		---
_____ 55	WO 98/11778	03/26/98	PCT	A01N	33/12	Yes
_____ 56	WO 98/42188	10/01/98	PCT	A01N	33/12	Yes

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 5 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

Other Documents

(including author (if listed), title, relevant pages, date of publication including at least month and year).

Examiner

Initial*

- _____ 57 *AHFS Drug Information*, pages 3107-3108, 1999.
- _____ 58 Physicians Desk Reference for Non-Prescription Durgs, Product Information, pgs. 643, 644, 649, 503, 507, and reference pages to Bactine, and Tanac, 1998.
- _____ 59 Winthrop Laboratories, ZEPHIRAN® CHLORIDE, Informational Brochure, July, 1980.
- _____ 60 Encyclopedia Britannica, Inc., Definitions of SKIN and SKIN, DISEASES OF, pgs. 603-609, 1970
- _____ 61 *DentalDots®* *What are they?*, located at "http://www.dentaldots.com/whatsadot.htm," page 1, web page dated July 14, 1999.
- _____ 62 *ViraMedx/Really Fast Relief for Herpes Related Outbreaks*, located at "http://www.viramedx.com/," 1 page, web page dated 6/28/99.
- _____ 63 *Cold Sores Healed in Less than 24 Hours Report Says*, located at "http://www.viramedx.com/news01.htm," 2 pages, web page dated 6/28/99.
- _____ 64 *Comparison of Zovirax, Valtrex, Famvir and ViraMedx*, located at "http://www.viramedx.com/compare..htm," 1 page, web page dated 6/28/99.

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

-
- _____ 65 *Herpes Treatment That Works on Genital Herpes Too*, located at "<http://www.viramedx.com/about.htm>," 1 page, web page dated 6/28/99.
- _____ 66 *Herpes Treatment Shows Promise Against Genital Herpes*, located at "<http://viramedx.com/study.htm>," 1 page, web page dated 6/28/99.
- _____ 67 *Results Against Clinical Strains of Herpes Simplex Virus*, located at "<http://www.ciramedx.com/labdata.htm>," 1 page, web page dated 6/28/99.
- _____ 68 *8 Year Study to Determine Effectiveness Against Herpes*, located at "<http://viramedx.com/clinicaldata.htm>," 1 page, web page dated 6/28/99.
- _____ 69 *8 Year Study to Determine Effectiveness Against Herpes*, located at "<http://www.ciramedx.com/results.htm>," 5 pages, web page dated 6/28/99.
- _____ 70 *8 Year Study to Determine Effectiveness Against Herpes*, located at "<http://www.viramedx.com/clinicalsum.htm>," 2 pages, web page dated 6/28/99.
- _____ 71 *Sigma Product Information Sheet, Benzalkonium Chloride*, located at "<http://www.sigma.sial.com/sigma/proddata/b1383.htm>.
- _____ 72 *ViraMedix, Antiviral Activity of Viracea® Against Acyclovir Resistant Strains of Herpes Simplex Virus (HSV)*, located at "<http://www.herpesccontrol.com/acyresist.htm>," by K.D. Thompson et al., The University of Chicago and Meryx Pharmaceutical, Chicago, Il (study results found at <http://www.herpesccontrol.com/figure3.htm>), © 1998.
- _____ 73 *ViraMedix News Release, Announcing the First OTC Treatment Proven to "Kill" the Herpes Virus that Causes Cold Sores, Fever Blisters and Related Outbreaks, Healing the Outbreak in Usually Less Than 24 Hours/Timely Introduction in Light of Recent News of the Spread of Herpes Caused Outbreaks and Just in Time*
-

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 7 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

for the Summer Sun Caused Outbreaks of Cold Sores, located at <http://www.herpesccontrol.com/news01.htm>, © 1998.

- _____ 74 Study Results, *Testimonials*, located at <http://www.herpesccontrol.com/results.htm>, © 1998.
- _____ 75 Berti, et al., *Transcutaneous Drug Delivery: A Practical Review*, Mayo Clin. Proc., Vol. 70, pages 581-586, June 1995.
- _____ 76 Choi, et al., *The Pretreatment Effect of Chemical Skin Penetration Enhancers in Transdermal Drug Delivery Using Iontophoresis*, Skin Pharmacol. Appl. Skin Physiol., pages 326-335, 1999.
- _____ 77 Comfort et al., *Enhanced Transport in a Therapeutic Transdermal System*, Biomaterials, Vol. 11, No. 9, pages 729-733, November 1990.
- _____ 78 Fang et al., *Development and Evaluation on Transdermal Delivery of Enoxacin Via Chemical Enhancers and Physical Iontophoresis*, Journal of Controlled Release, Vol. 54, pages 293-304, 1998.
- _____ 79 Fang et al., *Evaluation of Transdermal Iontophoresis of Enoxacin From Polymer Formulations: In Vitro Skin Permeation and In Vivo Microdialysis Using Wistar Rat as an Animal Model*, International Journal of Pharmaceutics 180, pages 137-149, 1999.
- _____ 80 Gismondo, et al., *Efficacia Antimicrobica e Sporidica di Varie Soluzioni Disinfettanti*, Minerva Medica, (Italy) Vol. 86, pages 21-32, January-February 1995 (English translation attached: *Antimicrobial and Sporidical Efficacy of Some Disinfectant Solutions*).
- _____ 81 James Alexander Corporation flyer, *Medicaine® Sting and Bite Relief Formula Flyer*, 1997.

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 8 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

-
- _____ 82 James Alexander Corporation flyer, *Medicaine® Topical Antiseptic*, 1997.
- _____ 83 James Alexander Corporation flyer, *Unit Dose Swabs*, 1997.
- _____ 84 Jin et al., *Effect of Application Volume of Ethanol-Isopropyl Myristate Mixed Solvent System on Permeation of Zidovudine and Probenecid Through Rat Skin*, Drug Development and Industrial Pharmacy, Vol. 26 No. 2, pages 193-198, 2000.
- _____ 85 Johnson, et al., *Supergistic Effects of Chemical Enhancers and Therapeutic Ultrasound on Transdermal Drug Delivery*, Journal of Pharmaceutical Sciences, Vol. 85, No. 7, pages 670-679, July 1996.
- _____ 86 Kanikkannan, et al., *Structure-Activity Relationship of Chemical Penetration Enhancers in Transdermal Drug Delivery*, *Current Medicinal Chemistry*, Vol. 7, No. 6, pages 593-608, 2000.
- _____ 87 Martindale, The Extra Pharmacopoeia, *Benzethonium Chloride/Benzyl Alcohol*, page 1119, Royal Pharmaceutical Society, 1996.
- _____ 88 Martindale, The Extra Pharmacopoeia, *Disinfectants and Preservatives*, pages 1114-1116, Royal Pharmaceutical Society, 1996.
- _____ 89 Martindale, The Extra Pharmacopoeia, *Ethyl Hydroxybenzoate/Magenta*, page 1137, Royal Pharmaceutical Society, 1996.
- _____ 90 Martindale, The Extra Pharmacopoeia, *Local Anesthetics*, pages 1317, 1320-1321, Royal Pharmaceutical Society, 1996.
- _____ 91 The Merck Index, An Encyclopedia of Chemicals, drugs, and Biologicals, Twelfth Edition, pages 177 and 180, 1996.
-

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 9 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

-
- _____ 92 Meyler's Side Effects of Drugs, An Encyclopedia of Adverse Reactions and Interactions, *Antiseptic Drugs and Disinfectants*, Chapter 24, pages 643-644 and 664-665, 1996.
- _____ 93 Sanofi Pharmaceuticals, Inc., *Zephiran® Chloride*, Brand of Benzalkonium Chloride, 1997.
- _____ 94 Williams, et al., *Skin Absorption Enhancers*, Critical Reviews in Therapeutic Drug Carrier Systems, 9(3,4), pages 305-353, 1992.
- _____ 95 Wu et al., *In Vitro Effect of Penetration Enhancers on Sodium Nonivamide Acetate in Rat Skin*, Biol. Pharm. Bull., Vol. 18, No. 12, pages 1790-1792, 1995.

References Cited by Applicants

While the filing of Information Disclosure Statements is voluntary, the procedure is governed by the guidelines of Section 609 of the Manual of Patent Examining Procedure and 37 C.F.R. §§ 1.97 and 1.98. To be considered a proper Information Disclosure Statement, Form PTO-1449 shall be accompanied by a copy of each listed patent or publication or other item of information and a translation of the pertinent portions of foreign documents (if an existing translation is readily available to the applicant), an explanation of relevance of each reference not in the English language, and should be submitted in a timely manner as set out in MPEP Sec. 609.

Examiners will consider all citations submitted in conformance with 37 C.F.R. § 1.98 and MPEP Sec. 609 and place their initials adjacent the citations in the spaces provided on this form. Examiners will also initial citations not in conformance with the guidelines which may have been considered. A reference may be considered by the Examiner for any reason whether or not the citation is in full conformance with the guidelines. A line will be drawn through a citation if it is not in conformance with the guidelines AND has not been considered. A copy of the submitted

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

EXPRESS MAIL LABEL NO.: EV 443087844 US

Form PTO-1449

Sheet 10 of 10

Applicant: B. Ron Johnson

Serial No.: 10/816,571

Att'y Docket No.: 15070.6.2

Filing Date: April 1, 2004

Confirmation No.: 1232

For: ANTI-INFECTIVE COMPOSITIONS, METHODS AND SYSTEMS
FOR TREATING PATHOGEN-INDUCED DISORDERED TISSUES

form, as reviewed by the Examiner, will be returned to the applicant with the next communication. The original of the form will be entered into the application file.

Each citation initialed by the Examiner will be printed on the issued patent in the same manner as references cited by the Examiner on Form PTO-892.

The reference designations "A1," "A2," etc. (referring to Applicant's reference 1, Applicant's reference 2, etc.) will be used by the Examiner in the same manner as Examiner's reference designations "A," "B," "C," etc. on Office Action Form PTO-1142.

W:\15070\6.2\MLA0000001922V001.doc

Examiner:

Date Considered:

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

B. Ron Johnson

) Art Unit
) 1614

i

)

S)

)

W:\15070\6.2\MLA0000001924V001.doc